D.
Project Planning

The project leader needs to ensure that project plans are well thought out, transparent to the organization, aggressive in time-to-market projections, have the backing of the various functional departments, and, if successful, support the achievement of the desired target profile/package insert.

By utilizing appropriate planning and control systems in his project, the successful project leader demonstrates leadership capability and creates and manages a myriad of mechanisms critical to the project leader and team throughout the drug development process. It is critical that, whatever tools are agreed upon to accomplish this objective, they are user friendly, useful to the project leader and the project team, and accessible to and used by all members of the team and others in the organization. It is anticipated and expected that these tools enable the team to develop integrated and aggressive project development plans with appropriate intermediate milestones and also ensure that the planning process is thorough enough to avoid downtime between critical path activities.

Project plans and schedules, which can be agreed upon, are critical prerequisites for obtaining individual commitments on projects. The project leader, team member, and functional manager must collectively know what tasks are committed to and when functional resources are required to perform and complete tasks as scheduled. For those individuals involved, progress on project plans must be appropriately monitored so that individual team members do not feel that their every working moment is being scrutinized by their organization. In addition, plans and schedule changes must be communicated to the organization periodically to ensure that all contributors stay aligned with project goals and performance expectations. Changes do indeed occur throughout development; it is imperative therefore that the project leader quickly communicate program modifications so that there are no unexpected surprises or misunderstandings with those whose commitments are affected by these changes.

To effectively lead a team, the team leader should be comfortable with and proficient in various planning, scheduling, and monitoring procedures and with mechanisms for developing budget estimates and control procedures. Project control is achieved in various ways, i.e., by setting mutually agreed objectives and goals, defining the various tasks which need to be performed, scheduling the tasks in concert with the functional departments in terms of resource requirements and availability, measuring project progress and performance in a clear, unbiased, and transparent manner, taking corrective action when progress is not made or when things do not go as

planned, resolving conflicts as appropriate or raising them in a professional manner to higher management levels for appropriate resolution, etc.

A sound, responsible, and agreed upon project plan, developed early in the development process, which supports the agreed target profile and is "revisited" periodically throughout the development process to ensure that it reflects the latest project status and best thinking of the team, is extremely important to a project's ultimate success and is a critical tool for the successful project leader and the international project team. This plan must reflect the most appropriate road map so that the corporation can maximize its return on investment. An integral part of this planning process, therefore, must be the early development of an agreed upon package insert, highlighting particularly those claims and attributes which are key for successful marketing. Based on these claims, the design of critical clinical studies can be focused to generate the relevant data.

Every team member must be involved in building the project plan. Measurable milestones must be defined against which team performance is assessed. In addition, mechanisms must be agreed to which allow detecting problems early enough, so that solutions are found to keep the project on track.

Project management techniques, such as PERT planning and critical path analysis, provide the project leader with the information required to stay on top of his project. For these tools to be most useful, however, all team members should have access to the same information as the project leader so that they understand where their "piece of the puzzle" fits and, more importantly, how well they and their team members are doing compared to the commitments that have been made. These planning techniques allow all project tasks to be optimally integrated and reduce project task duration through reduced overlapping of key activities, simulation modeling, and evaluation of contingency alternatives.

1.

Project Team Meetings

Meetings that are not well planned and well run are significant time wasters, serve little useful purpose, are a financial burden to the organization, and pose problems for the project leader in effectively synergizing interactions between team members and motivating them to meet high performance standards.

Often most people in an organization feel that there is insufficient quality time during the day to accomplish their daily objectives. Acknowledging and respecting this frustrating problem, the project leader's time

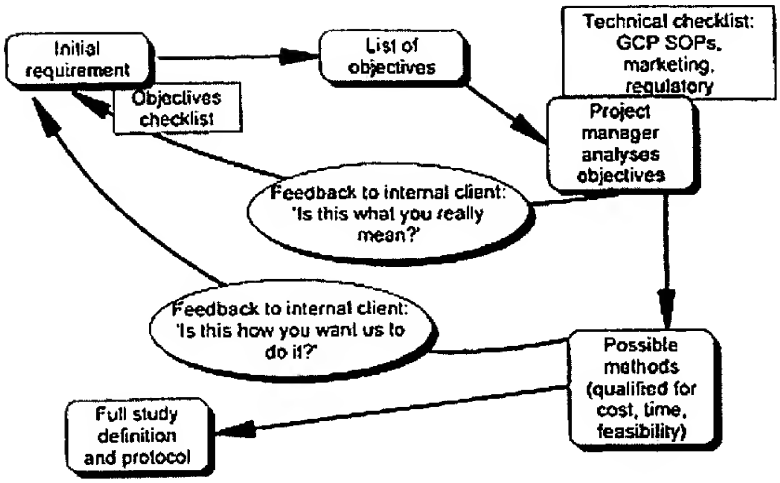

FIG. 7
Protocol definition: Alternative process. Courtesy of A. E. Berridge, Technical Management Development Ltd. (adapted).

as long as he is empowered by top management to carry out the negotiations required. Projects too often fail when this empowerment has not been carried out (such as the project coordinator).

Precisely the same process can be used at any level in clinical research, whether one is planning a single study or a whole clinical development program. In practice within pharmaceutical companies, the latter more often resembles Fig. 2, probably because, at this stage, much less is clear about the whole drug project. For single studies, the trap to avoid is using tried and tested methods on a production line basis. This can stifle creativity.

C. New Approaches to Written Procedures

Standard operating procedures (SOPs) have come a very long way since GCP entered common parlance over ten years ago. We are now seeing graphical representations of familiar processes, which aid understanding and compliance. We have already seen how SOPs provide essential tools at the project design stage, as they include standard checklists against which objectives and methods can be measured. Although clinical trials would stagnate without trying innovative methods, some standardization is a valuable time saver—if this were not so, our operating procedures would not be

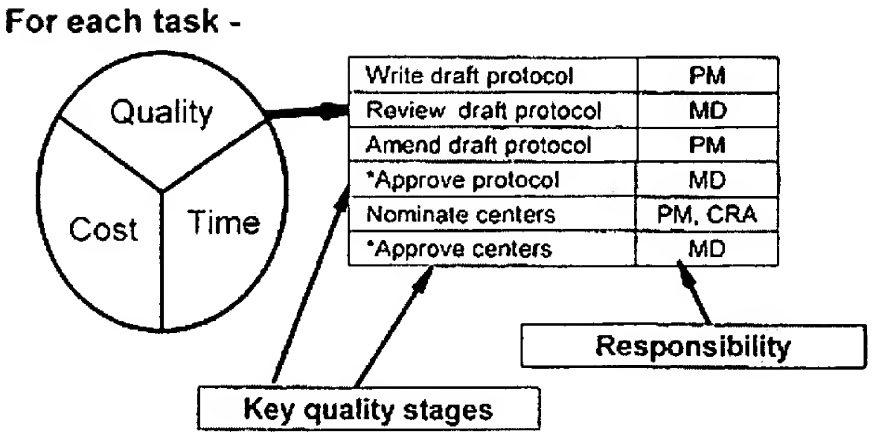

FIG. 8
Extract from clinical project template.

standard. The same applies to clinical project plans, so if we have standardized our practices we will be using common project structures for similar studies. Figure 8 shows part of a typical task list, which could apply with modification to a wide range of clinical trials and which can be included in an SOP as a template. Resources and duration for each task can be estimated for each new project, which can rapidly generate budgets and overall timescales. If the SOP is followed, this means that alternative studies, or those competing for resources, are directly comparable.

D. The Quality Dimension

As well as the highly structured world of GCP, which is benefiting from project management, we are now seeing the influence of a third management philosophy. Quality systems are not at all new. The modern, internationally recognized standard ISO 9000 has its roots in military equipment supply in the 1950s, and has progressed via BS 5750 in the United Kingdom [3]. In addition, the term "total quality management" is widely used (although not universally defined). Whatever quality system is being used, it is far more effective if it is integrated with existing management structures, rather than imposed as another layer. In the author's company, a contract research organization, two main actions have been taken to achieve this. First, all procedures have been restructured to comply with ISO 9000 and

with the existing project management system. Second, key quality steps are included in each clinical project plan, as shown in Fig. 8. Thus, the project management system ensures compliance with the quality and the GCP requirements of the study. In addition, with the study's critical path clearly highlighted, we are alerted to the tasks which must achieve quality approval first time, or they will delay the whole project.

E. Integrating GCP, Quality Systems, and Project Management

But as we have seen, one of the project manager's needs is to cope with new challenges from new project ideas. So it is not possible to standardize everything. Several pharmaceutical companies and CROs have approached this with procedures at several levels. Figure 9 shows one such approach. The more familiar SOPs contain completely standard material, with the project templates discussed above. At the working level, the varying requirements of individual studies can be accommodated with work procedures, which contain only material specific to that study, especially where a departure from standard practice is necessary. The baseline project plan for the study will be included as an appendix.

In between, other documents may be needed. For example, if the organization has any areas of specialization, a procedure for that special process may be written. Finally, governing all operations and projects are the quality manual and quality procedures, the first of which states policy and the second sets out methods for ensuring that quality policy is met.

One word of warning on quality systems: They are of no use unless they actually improve business performance. A recent survey [4] suggests that a

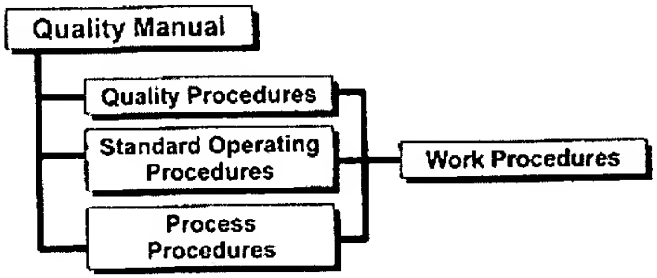

FIG. 9
Procedures for quality: As implemented in a contract research organization.

majority of companies across all industries have not achieved the expected business benefits from implementing ISO 9000. They are mostly forced to implement it because it was expected by their customers. Management must have clear objectives as to the improvements sought and the means to monitor these improvements, rather than using any quality system just for public relations or enhancing credibility.

1.
Procedures for Projects

There is one further SOP which does not seem to appear in any pharmaceutical company's register. This should cover project management methods. Examples of its content would be how project managers are appointed, how their authority (or empowerment) is defined, their responsibilities, the stages of setting up and running a clinical trial project—in fact, all the areas discussed in this chapter and many more.

Many companies will have such a document for running drug projects at the strategic level—indeed, this is the level at which the discipline is most advanced. However, it will be more difficult to achieve top level objectives if individual smaller projects, clinical trials and many others, are not managed effectively at the operational level. Thus, the clinical project manager has the tough job of ensuring good communication with other levels of management. It is hardly practical for strategic project managers to track all the tasks in every individual project, so agreement has to be achieved as to which key stages will provide the interface links to enable effective whole drug project tracking. Suitable stages would be best defined as deliverables, such as the approved protocol for a pivotal phase III trial or its final report.

F.
Getting Things Done—The Clinical Project Manager's Authority

At several stages in this chapter, the project manager's vital need for top management support has been emphasized. If this one need were satisfied, many companies which are now average performers, would be among the leaders in their fields. This is graphically illustrated by a survey carried out in 1994 [5]. Fifty chief executives from U.K. pharmaceutical companies were approached by letter to participate. The subject was top management's attitudes toward critical issues in delivering clinical trial results on time. In return for a brief interview, the participants were offered free consultancy to assess their current clinical project systems and to suggest changes. What is significant about the survey is not how many responded (four), but that the vast majority immediately delegated the matter to their